



US009199043B2

(12) **United States Patent**  
**Chattaraj et al.**

(10) **Patent No.:** **US 9,199,043 B2**  
(45) **Date of Patent:** **Dec. 1, 2015**

(54) **SYRINGE PISTON WITH CHECK VALVE SEAL**

(71) Applicant: **MEDTRONIC MINIMED, INC.**,  
Northridge, CA (US)

(72) Inventors: **Sarnath Chattaraj**, Simi Valley, CA  
(US); **Poonam S. Gulati**, La Canada,  
CA (US); **Lance P. Hoffman**, Los  
Angeles, CA (US); **Kiem Dang**,  
Thousand Oaks, CA (US)

(73) Assignee: **Medtronic MiniMed, Inc.**, Northridge,  
CA (US)

(\*) Notice: Subject to any disclaimer, the term of this  
patent is extended or adjusted under 35  
U.S.C. 154(b) by 159 days.

(21) Appl. No.: **14/041,039**

(22) Filed: **Sep. 30, 2013**

(65) **Prior Publication Data**

US 2014/0031749 A1 Jan. 30, 2014

**Related U.S. Application Data**

(62) Division of application No. 12/972,263, filed on Dec.  
17, 2010, now Pat. No. 8,574,201.

(60) Provisional application No. 61/289,243, filed on Dec.  
22, 2009.

(51) **Int. Cl.**

**A61M 5/315** (2006.01)

**A61M 5/36** (2006.01)

(52) **U.S. Cl.**

CPC ..... **A61M 5/36** (2013.01); **A61M 5/31511**  
(2013.01); **A61M 5/31513** (2013.01); **Y10T**  
**29/49826** (2015.01)

(58) **Field of Classification Search**

CPC ..... A61M 5/31513; A61M 5/31511;  
A61M 5/36

USPC ..... 604/22  
See application file for complete search history.

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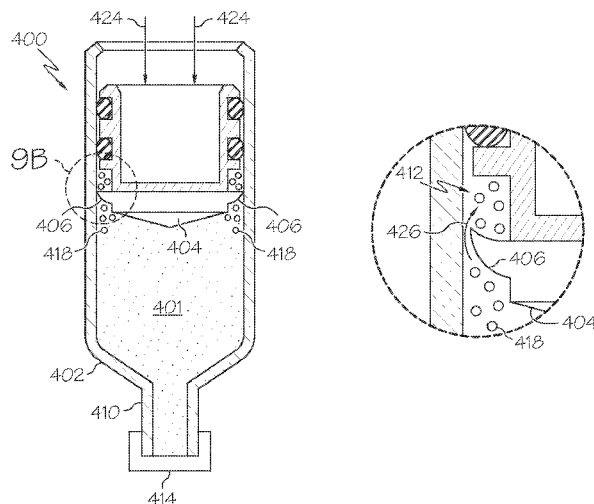
*Primary Examiner* — Edelmira Bosques

(74) *Attorney, Agent, or Firm* — Ingrassia Fisher & Lorenz,  
P.C.

(57) **ABSTRACT**

A fluid syringe of the type used with fluid infusion devices is presented here. The fluid syringe generally includes a barrel, a piston, and a check valve seal. The barrel has an interior wall and a sealed main fluid chamber. The piston is slidably coupled within the barrel, and the piston has a piston seal forming an interference fluid seal against the interior wall. The check valve seal is coupled to the piston, and it is located between the piston seal and the main fluid chamber. The check valve seal forms an interference fluid seal against the interior wall when the piston is unloaded, and it disengages the interior wall to allow gas flow from the main fluid chamber toward the piston seal when the piston is loaded.

**20 Claims, 8 Drawing Sheets**



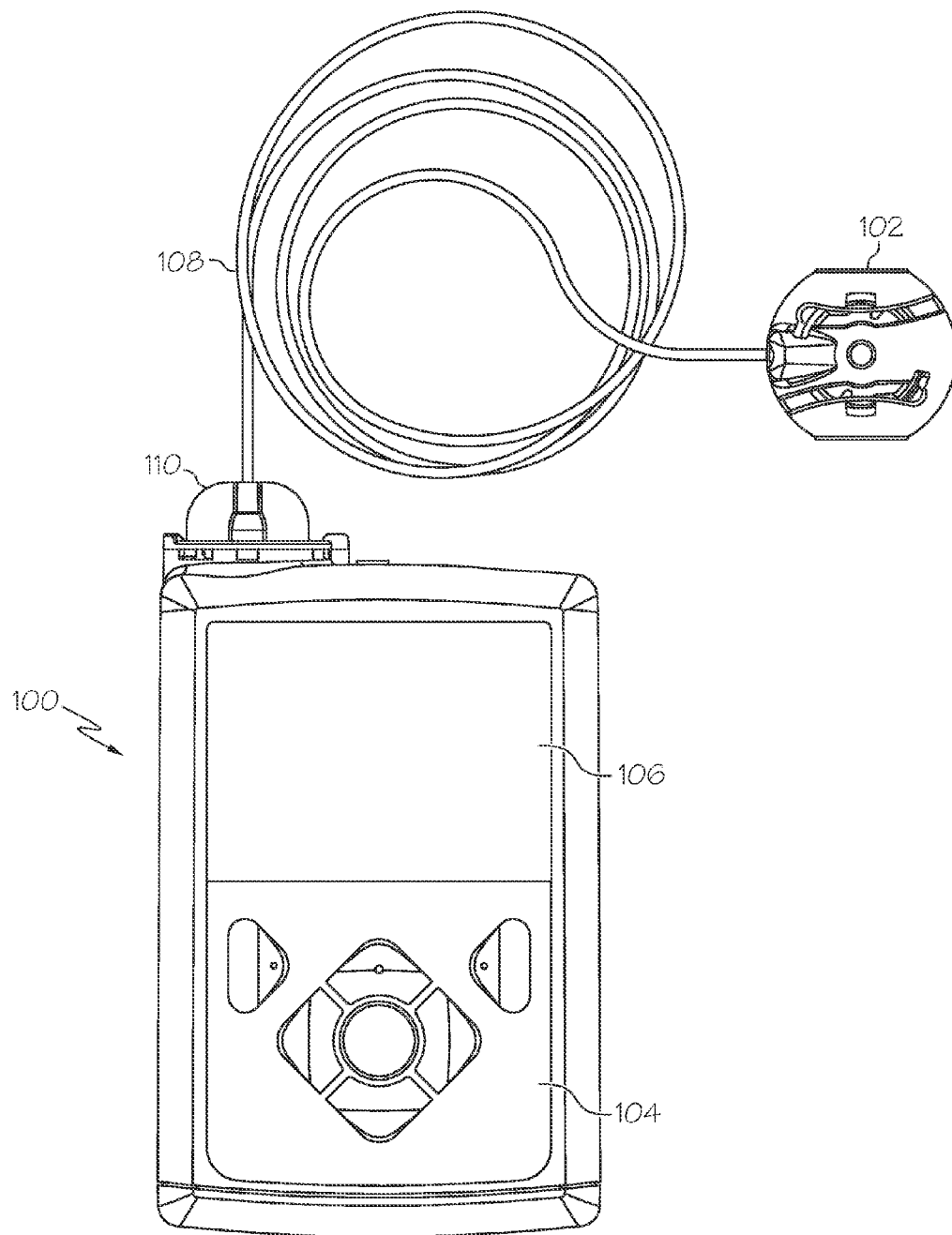
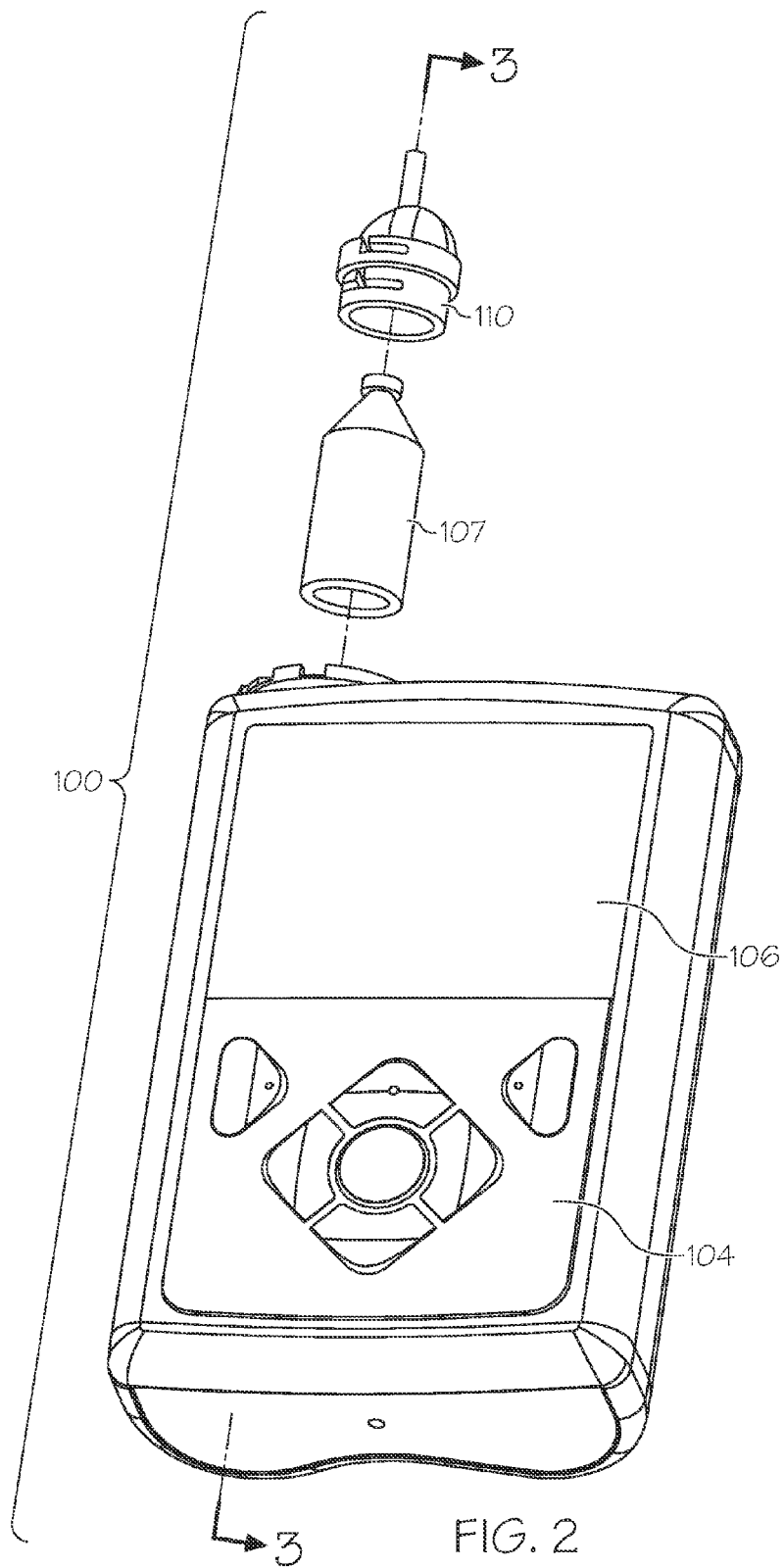


FIG. 1



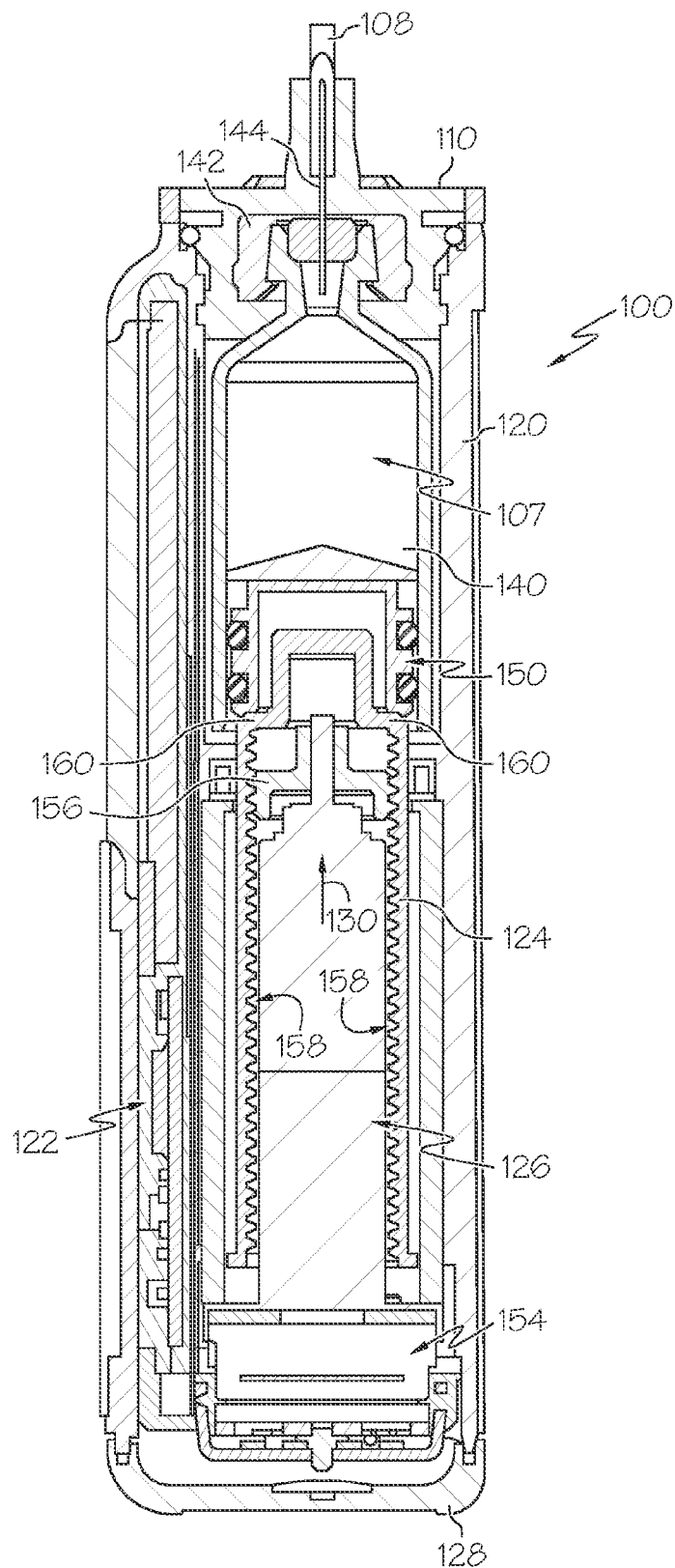


FIG. 3

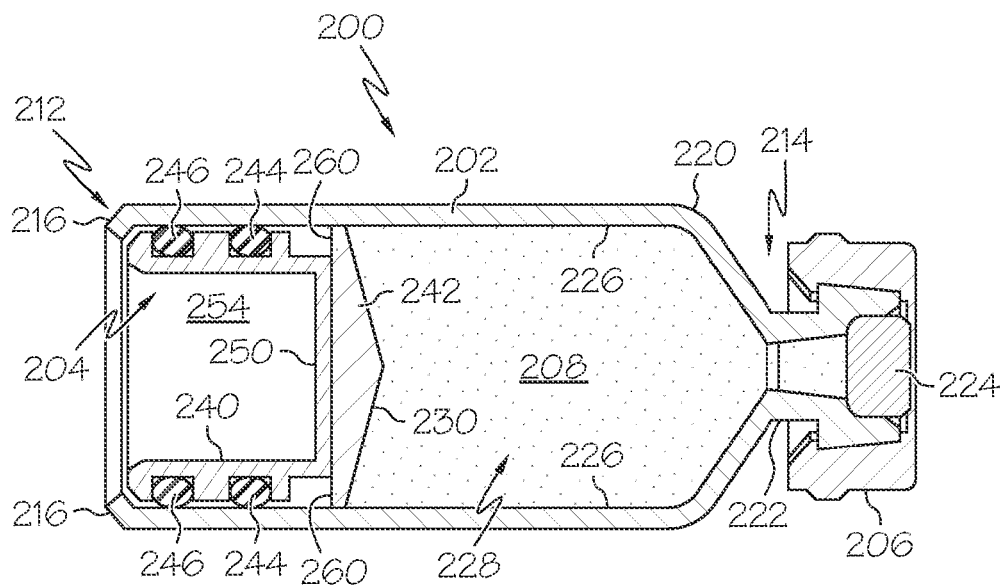


FIG. 4

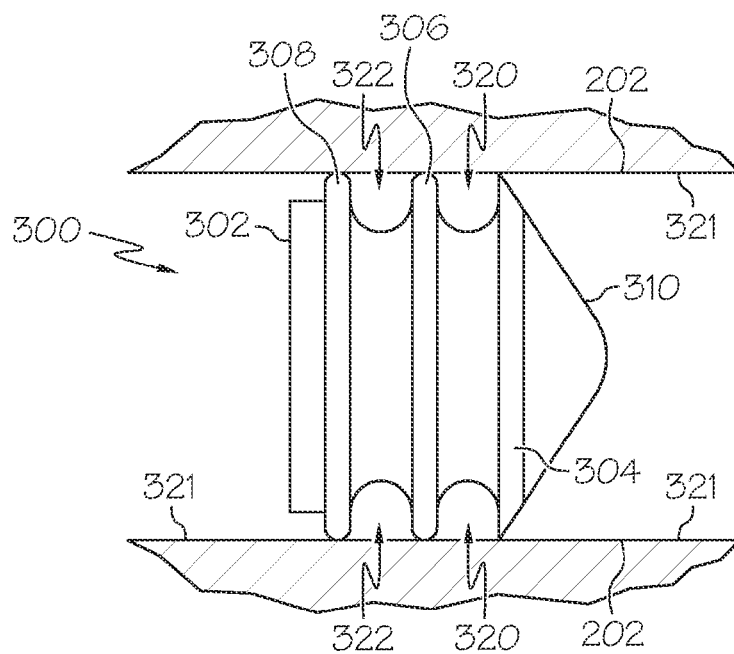


FIG. 5

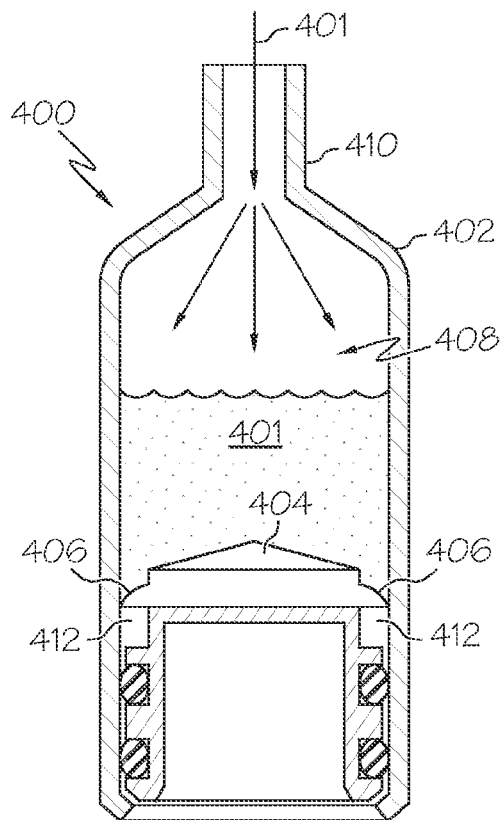


FIG. 6

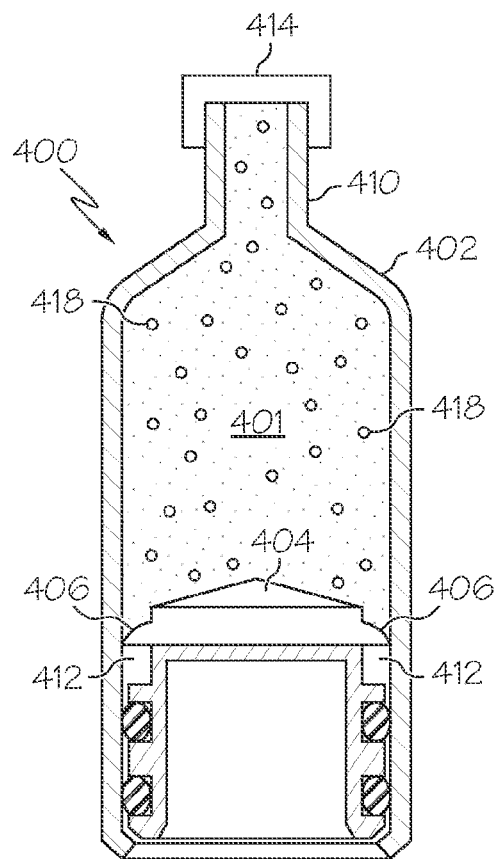


FIG. 7

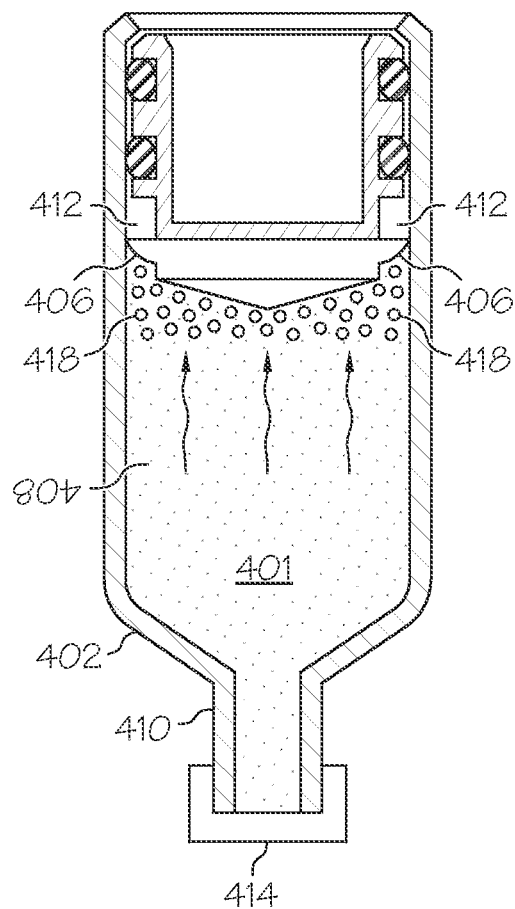


FIG. 8

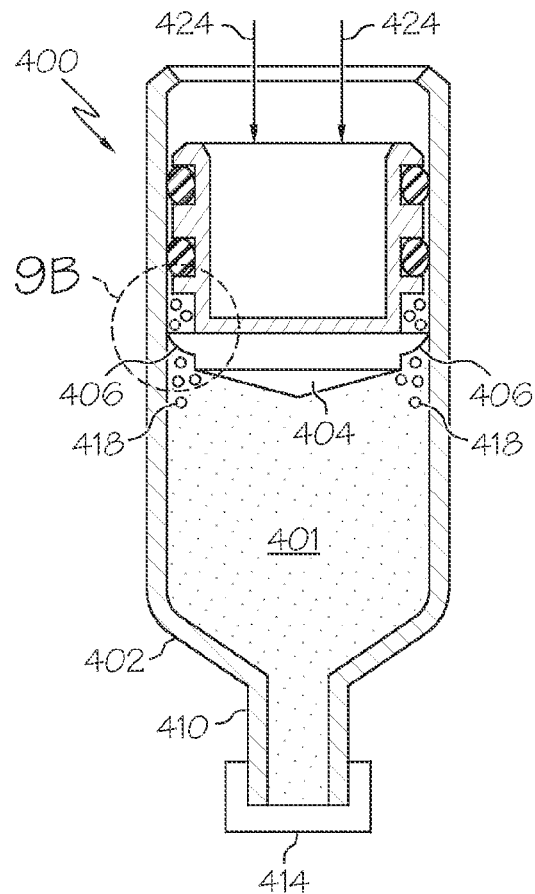


FIG. 9A

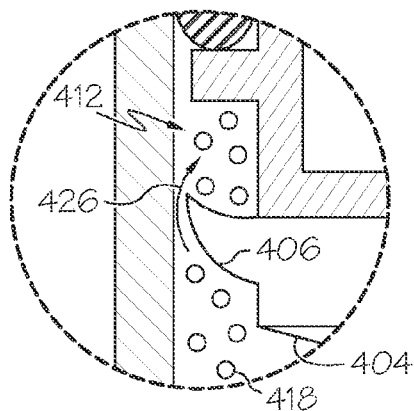


FIG. 9B



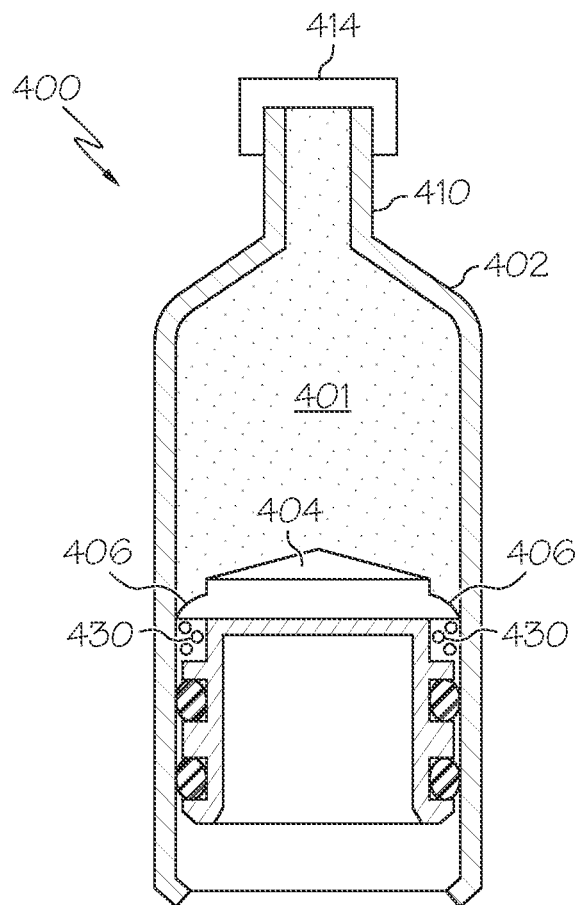


FIG. 10

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## SYRINGE PISTON WITH CHECK VALVE SEAL

### CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a divisional of U.S. patent application Ser. No. 12/972,263, filed Dec. 17, 2010, which claims the benefit of U.S. provisional patent application No. 61/289,243, filed Dec. 22, 2009 (now expired).

### TECHNICAL FIELD

Embodiments of the subject matter described herein relate generally to syringes and syringe pistons of the type used to deliver fluids, such as medication. More particularly, embodiments of the subject matter relate to a syringe piston having a check valve seal.

### BACKGROUND

Portable medical devices are useful for patients that have conditions that must be monitored on a continuous or frequent basis. For example, diabetics are usually required to modify and monitor their daily lifestyle to keep their body in balance, in particular, their blood glucose (BG) levels. Individuals with Type 1 diabetes and some individuals with Type 2 diabetes use insulin to control their BG levels. To do so, diabetics routinely keep strict schedules, including ingesting timely nutritious meals, partaking in exercise, monitoring BG levels daily, and adjusting and administering insulin dosages accordingly.

The prior art includes a number of fluid infusion devices and insulin pump systems that are designed to deliver accurate and measured doses of insulin via infusion sets (an infusion set delivers the insulin through a small diameter tube that terminates at, e.g., a cannula inserted under the patient's skin). In lieu of a traditional syringe, the patient can simply activate the insulin pump to administer an insulin bolus as needed, for example, in response to the patient's current BG level.

A typical infusion pump includes a housing, which encloses a pump drive system, a fluid containment assembly, an electronics system, and a power supply. The pump drive system typically includes a small motor (DC, stepper, solenoid, or other varieties) and drive train components such as gears, screws, and levers that convert rotational motor motion to a translational displacement of a piston in a reservoir, which may be in the form of a user-filled syringe or a pre-filled syringe. The fluid containment assembly typically includes the reservoir with the piston, tubing, and a catheter or infusion set to create a fluid path for carrying medication from the reservoir to the body of a user. The electronics system regulates power from the power supply to the motor. The electronics system may include programmable controls to operate the motor continuously or at periodic intervals to obtain a closely controlled and accurate delivery of the medication over an extended period.

The presence of air bubbles in a fluid syringe is undesirable for various reasons. Accordingly, air inside of user-filled syringes is usually expelled before the syringe is used. Moreover, air might be introduced into a pre-filled syringe during the filling and sealing processes. Therefore, various manufacturing techniques are implemented in an attempt to remove air from pre-filled syringes before sealing and/or to minimize the amount of air that gets introduced into the fluid. In this regard, conventional approaches often rely on vacuum filling and/or

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vacuum stoppering to remove or reduce the amount of air that gets trapped in the pre-filled syringes. Such techniques, however, involve specialized equipment, require additional handling of the product, and result in lower throughput.

Accordingly, it is desirable to have a different methodology for handling gas trapped inside of a fluid syringe. In addition, it is desirable to have a syringe piston design and a related syringe piston that can be manipulated to manage the presence of gas inside of the fluid chamber.

### BRIEF SUMMARY

An exemplary embodiment of a syringe piston is provided. The syringe piston includes a piston body having a fluid end and an actuator end opposite the fluid end, and a piston seal coupled to the piston body and located between the fluid end and the actuator end. The piston seal forms an interference fluid seal with an interior wall of a syringe barrel. The syringe piston also includes a check valve seal coupled to the piston body and positioned such that the piston seal is located between the check valve seal and the actuator end, and a gas entrapment zone defined between the check valve seal and the piston seal. The check valve seal allows one-way gas flow into the gas entrapment zone.

Also provided is an exemplary embodiment of a fluid syringe. The fluid syringe includes a syringe barrel comprising an interior wall and a sealed main fluid chamber, a syringe piston slidably coupled within the syringe barrel, and a check valve seal coupled to the syringe piston and located between the piston seal and the main fluid chamber. The syringe piston includes a piston seal forming an interference fluid seal against the interior wall. The check valve seal forms an interference fluid seal against the interior wall when the syringe piston is unloaded, and the check valve seal disengages the interior wall to allow gas flow from the main fluid chamber toward the piston seal when the syringe piston is loaded.

An exemplary embodiment of a method of manufacturing a fluid syringe is also provided. The method involves the fabrication of a syringe assembly having a syringe barrel having an interior wall and a main fluid chamber, a sealing cap having a penetrable membrane, a syringe piston slidably coupled within the syringe barrel and partially defining the main fluid chamber, and a liquid within the main fluid chamber. The syringe piston includes a piston seal forming an interference fluid seal against the interior wall, and a check valve seal located between the piston seal and the main fluid chamber. The method continues by maintaining the syringe assembly in a position that allows gas in the main fluid chamber to accumulate and rise toward the syringe piston and, after the gas in the main fluid chamber has settled at the check valve seal, applying a force to the syringe piston to move the syringe piston into the syringe barrel while maintaining the syringe assembly in the position. The check valve seal allows the gas to flow from the main fluid chamber into an entrapment zone defined between the piston seal, the check valve seal, and the interior wall. After the gas flows past the check valve seal into the entrapment zone, the method removes the force from the syringe piston to return the check valve seal to an unbiased state, such that the check valve seal retains the gas in the entrapment zone.

This summary is provided to introduce a selection of concepts in a simplified form that are further described below in the detailed description. This summary is not intended to identify key features or essential features of the claimed sub-

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ject matter, nor is it intended to be used as an aid in determining the scope of the claimed subject matter.

### BRIEF DESCRIPTION OF THE DRAWINGS

A more complete understanding of the subject matter may be derived by referring to the detailed description and claims when considered in conjunction with the following figures, wherein like reference numbers refer to similar elements throughout the figures.

FIG. 1 is a schematic representation of an embodiment of a fluid infusion device;

FIG. 2 is an exploded perspective view of the fluid infusion device shown in FIG. 1;

FIG. 3 is a cross-sectional view of the fluid infusion device (as viewed along line 3-3 in FIG. 2) with a fluid syringe installed therein;

FIG. 4 is a cross-sectional view of an exemplary embodiment of a fluid syringe, taken along its major longitudinal axis;

FIG. 5 is a side view of an exemplary embodiment of a syringe piston that is suitable for use with the fluid syringe shown in FIG. 3; and

FIGS. 6-10 are diagrams that illustrate a fluid syringe and a method of manufacturing it.

### DETAILED DESCRIPTION

The following detailed description is merely illustrative in nature and is not intended to limit the embodiments of the subject matter or the application and uses of such embodiments. As used herein, the word “exemplary” means “serving as an example, instance, or illustration.” Any implementation described herein as exemplary is not necessarily to be construed as preferred or advantageous over other implementations. Furthermore, there is no intention to be bound by any expressed or implied theory presented in the preceding technical field, background, brief summary or the following detailed description.

Certain terminology may be used in the following description for the purpose of reference only, and thus are not intended to be limiting. For example, terms such as “upper”, “lower”, “above”, and “below” refer to directions in the drawings to which reference is made. Terms such as “front”, “back”, “rear”, “side”, “outboard,” and “inboard” describe the orientation and/or location of portions of the component within a consistent but arbitrary frame of reference which is made clear by reference to the text and the associated drawings describing the component under discussion. Such terminology may include the words specifically mentioned above, derivatives thereof, and words of similar import. Similarly, the terms “first”, “second” and other such numerical terms referring to structures do not imply a sequence or order unless clearly indicated by the context.

The subject matter presented here relates to a check valve seal for a piston that is used to deliver a fluid (such as a liquid medication) from a fluid syringe to a person. Although the check valve seal concept can be utilized with user-filled syringes or pre-filled syringes, certain benefits described herein apply to pre-filled syringes that do not easily accommodate the expulsion of trapped air by the user. Accordingly, the following description focuses on pre-filled syringe embodiments. Moreover, the following description relates to a fluid infusion device of the type used to treat a medical condition of a patient. The infusion device is used for infusing fluid into the body of a user. The non-limiting examples described below relate to a medical device used to treat dia-

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betes (more specifically, an insulin pump), although embodiments of the disclosed subject matter are not so limited. Accordingly, the infused fluid is insulin in certain embodiments. In alternative embodiments, however, many other fluids may be administered through infusion such as, but not limited to, disease treatments, drugs to treat pulmonary hypertension, iron chelation drugs, pain medications, anti-cancer treatments, medications, vitamins, hormones, or the like. For or the sake of brevity, conventional features and characteristics related to infusion system operation, insulin pump and/or infusion set operation, fluid reservoirs, and fluid syringes may not be described in detail here. Examples of infusion pumps and/or related pump drive systems used to administer insulin and other medications may be of the type described in, but not limited to, United States patent application number 2009/0299290 A1 (the content of which is incorporated by reference in its entirety herein).

The check valve seal and the syringe assembly described here facilitate the containment of entrapped air, which may be introduced or created during the syringe filling process of a pre-filled syringe (after piston seating in the syringe barrel). Some conventional syringe pistons include two seals designed to protect the syringe-filled solutions from environmental conditions. A syringe with the two-seal design might contain solution and air within the syringe after piston installation. Air entrapped in the syringe is only vented by inverting the syringe and expelling a small quantity of solution/air mixture prior to needle injection.

In contrast to conventional syringe designs, the syringe piston described here includes an additional seal (the check valve seal) that faces the fluid chamber. The check valve seal is constructed to serve as a mechanical check valve between the syringe solution and the other piston seals. When positioned upright (i.e., the piston end of the syringe up), the entrapped air in the syringe will rise to the piston base. Thereafter, the piston is engaged (moved toward the solution in the fluid chamber) while the tip of the syringe is sealed. This mode of piston engagement allows entrapped solution/air to pass by the check valve seal into a cavity of the syringe, thereby containing the air and keeping the air out of the syringe solution. The check valve is designed to eliminate backflow of the solution/air mixture from the containment cavity to the syringe solution. Thus, when the syringe is capped or sealed, the check valve seal can be manipulated like a flap to accommodate fluid flow in one direction while inhibiting fluid flow in the other direction.

Referring now to the drawings, FIG. 1 is a schematic representation of an embodiment of a fluid infusion device **100**, and FIG. 2 is an exploded perspective view of the fluid infusion device **100**. FIG. 1 also shows an infusion set **102** coupled to the fluid infusion device **100**. The fluid infusion device **100** is designed to be carried or worn by the patient. The fluid infusion device **100** may leverage a number of conventional features, components, elements, and characteristics of conventional and well known fluid infusion devices. For example, the fluid infusion device **100** may incorporate some of the features, components, elements, and/or characteristics described in U.S. Pat. Nos. 6,485,465 and 7,621,893, the relevant content of which is incorporated by reference herein.

Referring to FIG. 1, the fluid infusion device **100** includes a user interface **104** that includes several buttons that can be activated by the user. These buttons can be used to administer a bolus of insulin, to change therapy settings, to change user preferences, to select display features, and the like. Although not required, the illustrated embodiment of the fluid infusion device **100** includes a display element **106**. The display ele-

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ment **106** can be used to present various types of information or data to the user, such as, without limitation: the current glucose level of the patient; the time; a graph or chart of the patient's glucose level versus time; device status indicators; etc. In some embodiments, the display element **106** is realized as a touch screen display element and, therefore, the display element **106** also serves as a user interface component.

The fluid infusion device **100** accommodates a fluid syringe **107** (see FIG. 2) for the fluid to be delivered to the user. Note that the words "syringe" and "reservoir" are used interchangeably herein; both refer to a fluid containment component that can be actuated to dispense fluid. A length of tubing **108** fluidly couples the fluid syringe **107** to the infusion set **102**. The tubing **108** extends from the fluid infusion device **100** to the infusion set **102**, which provides fluid communication with the body of the user. A removable cap or fitting **110** is suitably sized and configured to accommodate replacement of fluid reservoirs (which are typically disposable) as needed. In this regard, the fitting **110** is designed to accommodate the fluid path from the fluid syringe **107** to the tubing **108**.

FIG. 3 is a cross-sectional view of the fluid infusion device **100** with the fluid syringe **107** installed therein. The illustrated embodiment of the fluid infusion device **100** includes, without limitation: a housing **120**; an electronics assembly **122**; a slide **124**; and a drive system **126**. The housing **120** includes an opening adapted to receive the fluid syringe **107**. FIG. 3 illustrates the relationship between the drive system **126**, the slide **124**, and the fluid syringe **107**. FIG. 3 shows other components and features that are conventional in nature and/or are unrelated to the subject matter presented here. Moreover, it should be appreciated that FIG. 3 depicts the fluid infusion device **100** in a simplified manner. In practice, the fluid infusion device **100** could include additional elements, features, or components that are not shown or described in detail here.

The housing **120** has a hollow interior that accommodates the electronics assembly **122**, the fluid syringe **107**, the slide **124**, and the drive system **126**, which are enclosed within the housing **120** by a bottom portion **128**. In the illustrated embodiment, the slide **124**, the drive system **126**, and the fluid syringe **107** are aligned in an axial direction (indicated by arrow **130**). As described in greater detail below, the drive system **126** facilitates displacement of the slide **124** in the axial direction **130** to dispense fluid from the fluid syringe **107**.

The electronics assembly **122** includes control electronics that generally represent the hardware, firmware, processing logic and/or software (or combinations thereof) to control operation of the drive system **126** and other features of the fluid infusion device **100**. In an exemplary embodiment, the electronics assembly **122** includes one or more programmable controllers that may be programmed to control the various operations of the fluid infusion device **100**.

Depending on the embodiment, the fluid syringe **107** may be realized as a disposable reservoir, a user-filled reservoir, a pre-filled reservoir, a vial, a cartridge, or the like. In certain embodiments, the infused fluid is insulin, although many other fluids may be administered through infusion such as, but not limited to, HIV drugs, drugs to treat pulmonary hypertension, iron chelation drugs, pain medications, anti-cancer treatments, medications, vitamins, hormones, or the like. The fluid syringe **107** typically includes a barrel **140** that contains the fluid and is concentrically and/or coaxially aligned with the slide **124** (e.g., in the axial direction **130**) when the fluid syringe **107** is installed in the fluid infusion device **100**. The fluid delivery end of the fluid syringe **107** may include a

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suitably configured sealing cap **142** that cooperates with the fitting **110** in a way that allows the fitting **110** to secure the fluid syringe **107** in the housing **120**. When the fitting **110** is in place (as depicted in FIG. 3), displacement of the fluid syringe **107** in the axial direction **130** is inhibited. In an exemplary embodiment, the sealing cap **142** includes a penetrable membrane that is punctured by a delivery needle **144** of the fitting **110**. In this manner, the fitting **110** secures the fluid syringe **107** within the housing **120** and also serves to secure and connect the fluid syringe **107** to the infusion set tubing **108**.

The base end of the fluid syringe **107** (which is near the slide **124**) includes a syringe piston **150** positioned to push fluid from inside the barrel **140** of the fluid syringe **107** along a fluid path through the tubing **108** to a user. Note that the words "piston," "stopper," and "plunger" may be used interchangeably herein; these words all refer to the component that moves within the fluid syringe **107** to dispense fluid from the barrel **140**. The slide **124** is configured to mechanically couple or otherwise engage with the piston **150**, thereby becoming seated with the piston **150**. In operation, fluid is forced from the fluid syringe **107** via the tubing **108** as the drive system **126** is actuated to displace the slide **124** in the axial direction **130** toward the sealing cap **142**.

In an exemplary embodiment, the drive system **126** includes a motor assembly **154** and a drive screw **156**. The motor assembly **154** might include a motor and associated drive train components that convert rotational motor motion to a translational displacement of the slide **124** in the axial direction **130**, thereby engaging and displacing the piston **150** of the fluid syringe **107**. In some embodiments, the motor assembly **154** may also be powered to rewind the slide **124** in the opposing direction to accommodate removal and replacement of the fluid syringe **107**. Although the illustrated embodiment of the fluid infusion device **100** utilizes a coaxially aligned drive system **126**, the motor assembly **154** could instead be arranged in an offset or otherwise non-coaxial manner, relative to the longitudinal axis of the fluid syringe **107**.

The drive screw **156** mates with internal threads **158** internal to the slide **124**. When the motor assembly **154** is powered, the drive screw **156** rotates, and the slide **124** is forced to translate in the axial direction **130**. In an exemplary embodiment, the fluid infusion device **100** includes a feature that prevents the slide **124** from rotating when the drive screw **156** rotates. Thus, rotation of the drive screw **156** causes the slide **124** to extend or retract relative to the motor assembly **154**. When the fluid infusion device **100** is assembled and operational, the slide **124** contacts the piston **150** to engage the fluid syringe **107** and to control delivery of fluid from the fluid infusion device **100**. In an exemplary embodiment, a shoulder portion **160** of the slide **124** contacts or otherwise engages the piston **150** to displace the piston **150** in the axial direction **130**. In alternative embodiments (not shown), the slide **124** may include a threaded tip capable of being detachably engaged with internal threads formed in the piston **150**, as described in detail in U.S. Pat. Nos. 6,248,093 and 6,485,465, which are incorporated by reference herein.

FIG. 4 is a cross sectional view of an exemplary embodiment of a fluid syringe **200**, taken along its major longitudinal axis. Note that the fluid syringe **200** could be used as one suitable embodiment of the fluid syringe **107** shown in FIG. 2 and FIG. 3. This particular embodiment of the fluid syringe **200** is a pre-filled component, and FIG. 4 depicts the fluid syringe **200** in its pre-filled state prior to use and prior to installation into a fluid infusion device. The fluid syringe **200** generally includes, without limitation: a body or barrel **202**; a

piston **204**; a sealing cap **206**; and fluid **208** contained in the barrel **202**. For this example, the fluid **208** is a liquid medication such as insulin.

The barrel **202** can be formed from plastic, metal, glass, or the like. The barrel **202** has a base end **212** and a cap end **214** opposite the base end **212**. The base end **212** may include or cooperate with a retaining feature **216** that is designed to retain the piston **204** within the barrel **202**. The retaining feature **216** prevents the piston **204** from slipping out of the barrel **202** during manufacturing, shipping, storage, and handling of the fluid syringe **200**. The retaining feature **216** could be realized as an inward protruding rim or shoulder (as depicted in FIG. 4), as one or more keyway features, as a separate ring or other securing component that can be coupled to the fluid syringe **200**, or the like. The cap end **214** of the barrel **202** has a generally conical-shaped portion **220** which tapers to a neck region **222**. The sealing cap **206** is installed onto the neck region **222**, thereby forming a fluid-tight seal. In accordance with conventional reservoir designs, the sealing cap **206** includes a penetrable membrane **224** or an insert that can be pierced by a dispensing needle (as described above with reference to FIG. 3). The penetrable membrane **224** may also be referred to as a “septum.” The penetrable membrane **224** is designed to preserve its seal after it is pierced, to minimize leakage of fluid around the dispensing needle.

The barrel **202** has an interior wall **226** that defines a main fluid chamber **228** of the barrel **202**. As shown in FIG. 4, the fluid **208** resides within the main fluid chamber **228**. The main fluid chamber **228** is sealed after the fluid syringe **200** is filled with the fluid **208**; FIG. 4 depicts the main fluid chamber **228** in its sealed state. The end surface **230** of the piston **204** also defines the main fluid chamber **228**, which changes volume as the piston **204** is moved within the barrel **202**.

The piston **204** is slidably coupled within the barrel **202**, such that actuation of the piston **204** results in the delivery of the fluid **208** (when the main fluid chamber **228** is unsealed, for example, by piercing the membrane **224**). The piston **204** is suitably designed to form a fluid-tight barrier within the barrel **202** such that the fluid **208** does not leak from the base end **212** of the fluid syringe **200** and such that contaminants do not enter the main fluid chamber **228**. This particular embodiment of the piston **204** includes, without limitation: a piston body **240**; a check valve seal **242**; a piston seal **244**; and an end seal **246**. The end seal **246** may be realized as a second piston seal, or, in certain embodiments, the piston seal **244** and the end seal **246** may be one and the same. In yet other embodiments, three or more seals could be used with the check valve seal **242**.

The piston body **240** can be formed from plastic, metal, glass, or the like. The piston body **240** has a fluid end **250** and an actuator end **252** opposite the fluid end **250**. When the piston **204** is installed in the barrel **202**, the fluid end **250** is near the main fluid chamber **228**. The piston body **240** has a cavity **254** defined therein. The cavity **254** is shaped and sized to receive an actuation component, such as the tip of the slide **124** shown in FIG. 3. The exterior of the piston body **240** includes a number of features that accommodate the check valve seal **242**, the piston seal **244**, and/or the end seal **246**. In this regard, the exterior of the piston body **240** may include one or more of the following features or elements (formed therein, attached thereto, or coupled thereto), without limitation: ridges; shoulders; flanges; protrusions; cavities; rims; slots; holes; seats; grooves; and contours. For the embodiment illustrated in FIG. 4, the piston body **240** includes one circumferential groove that accommodates and retains the end seal **246** and another circumferential groove that accommodates and retains the piston seal **244**. The piston body **240**

may also include another groove or other feature for the check valve seal **242**. The illustrated embodiment, however, includes a check valve seal **242** that is mounted atop the piston body **240** such that the major outer surface of the check valve seal **242** faces the fluid **208**. Depending on its design, the check valve seal **242** could be coupled to the piston body **240** by way of a press-fit or snap-fit engagement.

The end seal **246** is coupled to the piston body **240** near the actuator end **252**, the check valve seal **242** is coupled to the piston body **240** near the fluid end **250**, and the piston seal **244** is coupled to the piston body **240** at a location between the fluid end **250** and the actuator end **252**. More specifically, the piston seal **244** is positioned between the check valve seal **242** and the end seal **246**, as shown in FIG. 4. The piston seal **244** is formed from a suitable material or composition that enables the piston seal **244** to form an interference fluid seal with the interior wall **226** of the barrel **202**. In this regard, the piston seal **244** is preferably formed from a resilient and pliable material such as rubber, plastic, urethane, or the like. In certain embodiments, the piston seal **244** is realized as a rubber o-ring that is coupled around the piston body **240**. The end seal **246** may be configured as described above for the piston seal **244** and, indeed, the end seal **246** is identical to the piston seal **244** in some embodiments.

When the piston **204** is installed in the barrel **202**, the check valve seal **242** forms an interference fluid seal against the interior wall **226** when the piston **204** is unloaded (i.e., no force is applied to the piston **204**). FIG. 4 depicts the check valve seal **242** in this nominal state. In certain embodiments, the check valve seal **242** includes a flap **260** that forms the interference fluid seal with the interior wall **226**. As explained below, the flap **260** is intentionally designed with asymmetric deflection characteristics. More specifically, the flap **260** is shaped, sized, and otherwise configured such that it is easier to deflect in the direction toward the actuator end **252**, and such that it is difficult to deflect in the direction away from the actuator end **252**. In other words, the flap **260** functions as a one-way fluid flow regulator. For this embodiment, the check valve seal **242** is tapered such that it is thinner at its outer perimeter (near the barrel **202**). In this regard, the check valve seal **242** may resemble an arrowhead.

In practice, the check valve seal **242** is preferably formed from a resilient and pliable material such as rubber, plastic, urethane, or the like. In certain embodiments, the check valve seal **242** is formed from a material or composition that is different than that used for the piston seal **244** and the end seal **246**. In this regard, the piston seal **244** and the end seal **246** may be formed from a resilient material having a first durometer, and the check valve seal **242** may be formed from a different resilient material having a second durometer (e.g., the second durometer is higher than the first durometer). Alternatively, the durometer of the piston seal **244** may be equal to the durometer of the check valve seal **242**. Consequently, the static, dynamic, and structural properties of the material used for the check valve seal **242** might be different than the static, dynamic, and structural properties of the material used for the piston seal **244** and the end seal **246**.

FIG. 5 is a side view of an exemplary embodiment of a syringe piston **300** that is suitable for use with the fluid syringe **200**. Many of the features and characteristics of the piston **300** are identical or similar to that described above for the piston **204**. Accordingly, common features and aspects of the pistons **204**, **300** will not be described in detail here. This embodiment of the piston **300** generally includes, without limitation: a piston body **302**; a check valve seal **304**; a piston seal **306**; and an end seal **308**. As described above for the piston **204**, the piston seal **306** and the end seal **308** fit within

respective grooves formed in the exterior of the piston body 302. Piston 300 also employs a third groove for the check valve seal 304. Thus, the check valve seal 304 may be realized as a ring-shaped seal that is stretched or otherwise manipulated for installation into its retaining groove. In this regard, the fluid end 310 of the piston body 302 is located above the check valve seal 304. This particular embodiment of the check valve seal 304 exhibits a sloped and angled profile, such that its perimeter is very thin at the point of contact with the barrel 202. Notably, the surface of the check valve seal 304 that faces the main fluid chamber slopes downward toward the barrel 202 and toward the end seal 308, as shown in FIG. 5. Of course, the shape, size, and profile of the check valve seal 304 could vary from that shown here.

The pistons 204, 300 are suitably configured with various fluid, gas, and/or buffer zones or chambers defined between the different seals. As best shown in FIG. 5, the piston 300 includes a fluid entrapment zone 320 defined between the check valve seal 304, the piston seal 306, and the interior wall 321 of the barrel 202. In typical implementations, the fluid entrapment zone 320 is utilized as a collection and retention chamber for unwanted air or other gas that might be present after filling the fluid syringe. As described in more detail below, under certain conditions the check valve seal 304 allows one-way fluid flow into the fluid entrapment zone 320 when the syringe piston 300 is installed in the barrel 202. In this regard, when the fluid syringe is deployed and unsealed for purposes of dispensing fluid, the check valve seal 304 forms an interference fluid seal against the interior wall 321 of the barrel 202 and inhibits or prevents fluid flow from the fluid entrapment zone 320 into the main fluid chamber within the barrel 202.

The piston 300 may also include a buffer zone 322 or chamber defined between the piston seal 306, the end seal 308, and the interior wall 321 of the barrel 202. The buffer zone 322 is helpful to inhibit or prevent the incursion of outside contaminants or moisture into the main fluid chamber within the barrel 202. In certain embodiments, the piston seal 306 inhibits or prevents fluid flow from the fluid entrapment zone 320 toward the end seal 308. In other words, the piston seal 306 inhibits or prevents fluid flow from the fluid entrapment zone 320 into the buffer zone 322.

The check valve seals 242, 304 described here facilitate the handling of air or other gas that might become trapped in a pre-filled fluid syringe during manufacturing. In this regard, FIGS. 6-10 are diagrams that illustrate an exemplary embodiment of a fluid syringe and an exemplary method of manufacturing it. FIG. 6 depicts a syringe assembly 400 as it is being filled with a liquid 401. The syringe assembly 400 includes a barrel 402, a piston 404, and a check valve seal 406 having the features and characteristics described above. The piston 404 is depicted in a simplified schematic form in FIGS. 6-10 for the sake of clarity.

As shown in FIG. 6, the main fluid chamber 408 is filled by dispensing the liquid 401 into the neck region 410 of the barrel 402, which is open or uncapped. In practice, the piston 404 is positioned at or near the bottom of the barrel 402 during the filling operation. This position (shown in FIG. 6) may be considered to be the filling position of the piston 404. The check valve seal 406 cooperates with and seals against the interior wall of the barrel 402 while the liquid 401 is dispensed into the barrel 402. Consequently, the liquid 401 remains above the check valve seal 406 and it does not leak into the fluid containment zone 412. The liquid 401 is dispensed into the neck region 410 until the barrel 402 is filled. Thereafter, the manufacturing process may install a sealing cap 414 onto the neck region 410 to seal the liquid 401 inside

the barrel 402 (see FIG. 7). At this time, the barrel 402 and the main fluid chamber are closed (sealed) and the piston 404 is unloaded and in an uncompressed state. Under these conditions the check valve seal 406 maintains the seal against the interior wall of the barrel 402, as shown in FIG. 7.

Air or other gas might be introduced into the liquid during the filling process. Moreover, some of this gas can be trapped inside the barrel 402 after securing the sealing cap 414 in place. In this regard, FIG. 7 schematically depicts gas bubbles 418 dispersed throughout the liquid 401 inside the barrel 402. The manufacturing process may continue by inverting the syringe assembly 400 and maintaining it in a position that allows gas in the main fluid chamber to accumulate and rise toward the piston 404 (see FIG. 8). In practice, the syringe assembly 400 should be held in an upright (vertical) position with the check valve seal 406 above the sealing cap 414, to allow the gas bubbles 418 in the liquid 401 to rise, accumulate, and settle at or near the check valve seal 406. The wavy arrows in FIG. 8 represent the rising and settling of the gas near the check valve seal 406. Depending upon the specific manufacturing procedure, the syringe assembly 400 may be held in the settling position without applying any additional stimuli. Alternatively, it may be desirable to accelerate the settling of the gas (if possible) by gently agitating the syringe assembly 400, by changing the surrounding temperature, or the like.

After the gas in the barrel 402 has settled at the check valve seal 406, an actuation force is applied to the piston 404 (while maintaining the syringe assembly 400 in its inverted position). The arrows 424 in FIG. 9 represent the actuation force. The actuation force 424 causes the piston 404 to slightly move into the barrel 402 toward the sealing cap 414, as depicted in FIG. 9. The compression of the piston 404 at this time causes the check valve seal 406 to temporarily disengage from the interior wall of the barrel, as shown in the detail section of FIG. 9. Note that disengagement of the check valve seal 406 in this manner occurs because the barrel 402 and the main fluid chamber are sealed and the piston is loaded under a compressive force. Under these conditions, the check valve seal 406 allows the gas to flow from the main fluid chamber into the fluid entrapment zone 412. The arrow 426 in the detail section of FIG. 9 indicates the flow path of the gas past the check valve seal 406. The piston 404 can be moved into the barrel 402 as far as needed to entrap the desired amount of gas within the fluid entrapment zone 412.

After the desired amount of gas flows past the check valve seal 406 and into the fluid entrapment zone 412, the actuation force 424 is removed from the piston 404 to return the check valve seal 406 to its nominal and unbiased state. FIG. 10 depicts the syringe assembly after removal of the actuation force 424. In this state the check valve seal 406 retains the captured gas 430 in the fluid entrapment zone 412. At this time, manufacturing of the syringe assembly 400 can be completed as desired. The check valve seal 406 is suitably configured to maintain the captured gas 430 in the fluid entrapment zone 412 while fabrication of the syringe assembly 400 is completed, during packaging, shipping, and storage of the syringe assembly 400, and during user manipulation and installation of the syringe assembly 400. In this regard, the captured gas 430 should remain in the fluid entrapment zone 412 after the syringe assembly 400 is installed in a fluid infusion device (see FIG. 3). Moreover, the captured gas 430 remains in the fluid entrapment zone 412 after the syringe assembly 400 has been opened (unsealed) for purposes of dispensing fluid. In particular, the check valve seal 406 maintains its seal against the interior wall of the barrel 402 when the main fluid chamber is unsealed (e.g., the sealing cap 414

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has been penetrated), and when the piston is compressed for purposes of delivering the liquid out of the barrel **402**.

Accordingly, the check valve seals described above can be utilized with a piston of a fluid reservoir such that the reservoir can be pre-filled in an easy and cost efficient manner without performing time consuming and complicated procedures intended to completely eliminate the presence of gas or air during filling. Rather, the check valve seals allow a manufacturer of pre-filled reservoirs to tolerate and accommodate some amount of gas that might be trapped inside the sealed reservoirs. The check valve seals, along with the manufacturing procedure described above, can be used to collect and capture the trapped gas without having to perform a post-fill venting or priming operation.

While at least one exemplary embodiment has been presented in the foregoing detailed description, it should be appreciated that a vast number of variations exist. It should also be appreciated that the exemplary embodiment or embodiments described herein are not intended to limit the scope, applicability, or configuration of the claimed subject matter in any way. Rather, the foregoing detailed description will provide those skilled in the art with a convenient road map for implementing the described embodiment or embodiments. It should be understood that various changes can be made in the function and arrangement of elements without departing from the scope defined by the claims, which includes known equivalents and foreseeable equivalents at the time of filing this patent application.

What is claimed is:

**1.** A syringe piston comprising:

a piston body having a fluid end and an actuator end opposite the fluid end;

a piston seal coupled to the piston body and located between the fluid end and the actuator end, wherein the piston seal forms an interference fluid seal with an interior wall of a syringe barrel;

a check valve seal coupled to the piston body and positioned such that the piston seal is located between the check valve seal and the actuator end, the check valve seal having a major outer surface that faces a main fluid chamber of the syringe barrel; and

a gas entrapment zone defined between the check valve seal and the piston seal, wherein the check valve seal allows one-way gas flow from the main fluid chamber of the syringe barrel and into the gas entrapment zone, and the piston seal inhibits or prevents gas flow from the gas entrapment zone.

**2.** The syringe piston of claim **1**, wherein the check valve seal comprises a flap that forms an interference fluid seal with the interior wall of the syringe barrel under nominal operating conditions.

**3.** The syringe piston of claim **1**, wherein the check valve seal inhibits gas flow from the gas entrapment zone into the syringe barrel.

**4.** The syringe piston of claim **1**, further comprising an end seal coupled around the piston body and positioned such that the piston seal is located between the check valve seal and the end seal.

**5.** The syringe piston of claim **4**, wherein the piston seal inhibits gas flow from the gas entrapment zone toward the end seal.

**6.** The syringe piston of claim **4**, further comprising a buffer zone defined between the piston seal and the end seal.

**7.** The syringe piston of claim **1**, wherein:

the piston seal is formed from a first resilient material having a first durometer; and

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the check valve seal is formed from a second resilient material having a second durometer that is different than the first durometer.

**8.** The syringe piston of claim **1**, wherein:

the check valve seal comprises a flap that cooperates with the interior wall of the syringe barrel;

the flap seals against the interior wall of the syringe barrel when the syringe barrel is closed and the syringe piston is uncompressed;

the flap disengages the interior wall of the syringe barrel when the syringe barrel is closed and the syringe piston is compressed; and

the flap seals against the interior wall of the syringe barrel when the syringe barrel is open and the syringe piston is compressed for purposes of dispensing fluid.

**9.** A syringe piston comprising:

a piston body having a fluid end and an actuator end opposite the fluid end;

a piston seal coupled to the piston body and located between the fluid end and the actuator end, wherein the piston seal forms an interference fluid seal with an interior wall of a syringe barrel;

a check valve seal coupled to the piston body and positioned such that the piston seal is located between the check valve seal and the actuator end, the check valve seal having a major outer surface that faces a main fluid chamber of the syringe barrel, and the check valve seal comprising a flap having asymmetric deflection characteristics such that the flap is easier to deflect in a direction toward the actuator end, relative to deflection in a direction away from the actuator end; and

a gas entrapment zone defined between the check valve seal and the piston seal, wherein the check valve seal allows one-way gas flow from the main fluid chamber of the syringe barrel and into the gas entrapment zone, and the piston seal inhibits or prevents gas flow from the gas entrapment zone.

**10.** The syringe piston of claim **9**, wherein the flap functions as a one-way fluid flow regulator.

**11.** The syringe piston of claim **9**, wherein the flap forms an interference fluid seal with the interior wall of the syringe barrel under nominal operating conditions.

**12.** The syringe piston of claim **9**, wherein the check valve seal inhibits gas flow from the gas entrapment zone into the syringe barrel.

**13.** The syringe piston of claim **9**, further comprising an end seal coupled around the piston body and positioned such that the piston seal is located between the check valve seal and the end seal.

**14.** The syringe piston of claim **9**, wherein:

the piston seal is formed from a first resilient material having a first durometer; and

the check valve seal is formed from a second resilient material having a second durometer that is different than the first durometer.

**15.** The syringe piston of claim **9**, wherein:

the flap cooperates with the interior wall of the syringe barrel;

the flap seals against the interior wall of the syringe barrel when the syringe barrel is closed and the syringe piston is uncompressed;

the flap disengages the interior wall of the syringe barrel when the syringe barrel is closed and the syringe piston is compressed; and

the flap seals against the interior wall of the syringe barrel when the syringe barrel is open and the syringe piston is compressed for purposes of dispensing fluid.

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16. A syringe piston comprising:  
 a piston body having a fluid end and an actuator end opposite the fluid end;  
 a piston seal coupled to the piston body and located between the fluid end and the actuator end, wherein the piston seal forms an interference fluid seal with an interior wall of a syringe barrel;  
 a check valve seal coupled to the piston body and positioned such that the piston seal is located between the check valve seal and the actuator end, the check valve seal having a major outer surface that faces a main fluid chamber of the syringe barrel, and the check valve seal comprising a flap that cooperates with the interior wall of the syringe barrel; and  
 a gas entrapment zone defined between the check valve seal and the piston seal, wherein the check valve seal allows one-way gas flow from the main fluid chamber of the syringe barrel and into the gas entrapment zone, the check valve seal inhibits gas flow from the gas entrapment zone into the syringe barrel, and the piston seal inhibits or prevents gas flow from the gas entrapment zone; wherein  
 the flap seals against the interior wall of the syringe barrel when the syringe barrel is closed and the syringe piston is uncompressed;

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the flap disengages the interior wall of the syringe barrel when the syringe barrel is closed and the syringe piston is compressed; and

the flap seals against the interior wall of the syringe barrel when the syringe barrel is open and the syringe piston is compressed for purposes of dispensing fluid.

17. The syringe piston of claim 16, further comprising an end seal coupled around the piston body and positioned such that the piston seal is located between the check valve seal and the end seal.

18. The syringe piston of claim 17, wherein the piston seal inhibits gas flow from the gas entrapment zone toward the end seal.

19. The syringe piston of claim 17, further comprising a buffer zone defined between the piston seal and the end seal.

20. The syringe piston of claim 16, wherein:

the piston seal is formed from a first resilient material having a first durometer; and

the check valve seal is formed from a second resilient material having a second durometer that is different than the first durometer.

\* \* \* \* \*